

Subject:	<u>Central (Hip or Spine) Bone Mineral Density Testing Measurement and Screening for Vertebral Fractures Using Dual Energy X Ray Absorptiometry</u>
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Description

This document addresses central bone mineral density (BMD) measurements and vertebral fracture assessment (VFA) using dual energy X Ray absorptiometry (DEXA). This document does not address peripheral (for example, forearm, finger, and heel) bone density measurements or bone density testing by computed tomography.

Bone mineral density (BMD) measurement is a non-invasive technique that is used to measure bone mineral content and bone mineral density. Its primary role is to detect osteoporosis, and to predict the risk of fractures and to assess the response to, or efficacy of, medication for the treatment of osteoporosis. DEXA is the most commonly used technique to measure BMD. VFA (formerly referred to as vertebral morphometry, instant vertebral assessment and vertebral absorptiometry) uses central DEXA to obtain images of the thoracic and lumbar spine to identify vertebral fractures. Screening for vertebral fractures can be done at the same time a subject is undergoing assessment of BMD.

BMD can be measured in a variety of locations (central or peripheral) using several different techniques. DEXA is the most commonly used technique to measure BMD. Lateral spine images can also be obtained using DEXA, and thus it is possible to screen for vertebral fractures at the same time a subject is undergoing assessment of BMD. The following techniques can be used to obtain BMD measurements:

- Central (hip or spine) BMD; or
- Peripheral (appendicular skeleton) BMD:
 - heel densitometry;

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- peripheral dual energy x-ray absorptiometry (pDEXA);
- radiographic absorptiometry of the fingers;
- single energy X-ray absorptiometry (SEXA);
- single photon absorptiometry (SPA);
- dual X-ray and laser (DXL).

Note(s): For information regarding peripheral bone density studies including the use of heel densitometry, peripheral dual energy x-ray absorptiometry (pDEXA), radiographic absorptiometry of the fingers, single energy X-ray absorptiometry (SEXA), single photon absorptiometry (SPA), and dual X-ray and laser (DXL), please refer to:

- RAD.00004 Peripheral Bone Mineral Density Measurement

Clinical Indications

Medically Necessary:

I. CENTRAL BONE MINERAL DENSITY MEASUREMENTS:

A. Initial Central Bone Mineral Density MeasurementsINITIAL CENTRAL BONE MINERAL DENSITY MEASUREMENTS

1. In general, a baseline central bone mineral density (BMD) measurement may be considered **medically necessary** whenever there is a reasonable expectation that the findings will be abnormal and a treatment decision may be influenced by the outcome of the test.
2. Specifically, an initial (baseline) central (hip or spine) bone density measurement is considered **medically necessary** when performed in **any** of the following settings:
 - 1.a. Screening for osteoporosis in postmenopausal individuals 65 years of age or older; **or**
 - 2.b. Screening for osteoporosis in men 70 years of age or older; **or**
 - 3.c. Individuals (male or female) with clinical evidence of vertebral osteoporosis as indicated by any of the following:
 - 4.a. Decrease in height of greater than 1.5 inches; **or**
 - 2.b. Presence of kyphosis; **or**

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3.■ X-ray identification of vertebral compression fractures, osteoporosis, or osteopenia (low bone mass).

4.d. Individuals who are known or suspected to have a condition that may underlie the osteoporosis, including but not limited to the following:

- 1.■ Anorexia nervosa; **or**
- 2.■ Chemotherapeutic agents which affect bone density; **or**
- 3.■ Chronic liver disease; **or**
- 4.■ Chronic renal failure; **or**
- 5.■ Chronic use of anti-convulsants (particularly Dilantin); **or**
- 6.■ Chronic use of heparin; **or**
- 7.■ Cushing's Syndrome (hypercortisolism); **or**
- 8.■ Fragility or pathologic fracture; **or**
- 9.■ Hypercalciuria; **or**
- 10.■ Hyperthyroidism; **or**
- 11.■ Hypothyroidism; **or**
- 12.■ Hypogonadism; **or**
- 13.■ Inflammatory bowel disease; **or**
- 14.■ Lupron therapy in men; **or**
- 15.■ Malabsorption syndromes; **or**
- 16.■ Malignancies (multiple myeloma); **or**
- 17.■ Organ transplantation; **or**
- 18.■ Osteogenesis imperfecta; **or**
- 19.■ Prolonged amenorrhea (6 months duration or longer); **or**
- 20.■ Prolonged immobilization; **or**
- 21.■ Radiologic evidence of osteopenia; **or**
- 22.■ Receiving aromatase inhibitor therapy; **or**
- 23.■ Receiving long-term glucocorticoid therapy (greater than three months or the equivalent dose of 7.5 mg prednisone [or 30 mg cortisone] or more per day), provided intervention is an option; **or**
- 24.■ Rheumatoid arthritis; **or**
- 25.■ Untreated premature menopause; **or**

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26. Vertebral abnormalities.

B. Repeat Central Bone Mineral Density Measurements **REPEAT CENTRAL BONE MINERAL DENSITY MEASUREMENTS**

1. Individuals Not On Therapy Related To Osteoporosis:

- A.a. For those without significant osteopenia or not at high risk for accelerated bone loss, repeat testing is considered **medically necessary** every 3 to 5 years.
- B.b. For individuals with significant osteopenia or at high risk for accelerated bone loss including individuals with any one of the conditions listed in bullet "C" above, repeat measurement is considered **medically necessary** every 2 to 3 years.
- C.c. Individuals who have an initial BMD measurement well above the minimal desirable level may not need a repeat measurement.

2. Individuals On Therapy Related To Osteoporosis:

- a. Repeat measurements of BMD as a technique to monitor response to therapy for osteoporosis are considered **medically necessary** when performed at intervals of 2 years or greater.

C. CENTRAL BONE DENSITY MEASUREMENTS for ASYMPTOMATIC HYPERPARATHYROIDISM

- 1. Bone density measurement using the spine (trabecular bone), or hip (mixed cortical and trabecular bone) is considered **medically necessary** when performed for individuals (male or female) with asymptomatic primary hyperparathyroidism (PHPT) where consideration for surgery is in large part determined by bone density level.

II. VERTEBRAL FRACTURES USING DUAL X-RAY ABSORPTIOMETRY

A. Screening for vertebral fractures using dual x-ray absorptiometry as an adjunct to bone mineral density measurement is considered **medically necessary** for the following:

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- A.1. Women greater than or equal to 70 years of age and men greater than or equal to 80 years of age if the BMD T score is less than or equal to -1.0 at the spine, hip or femoral neck; **or**
- B.2. Women 65 to 69 years of age and men age 70 to 79 years of age if the BMD T score is less than or equal to -1.5 at the spine, hip or femoral neck; **or**
- C.3. Postmenopausal women and men greater than or equal to 50 years of age with **any** of the following risk factors:
 - 1.a. Low trauma fracture at age 50 years or older; **or**
 - 2.b. Historical height loss* of greater than or equal to 1.5 inches; **or**
 - 3.c. Prospective height loss§ of 0.8 inch or more; **or**
 - 4.d. Recent or ongoing treatment with glucocorticoids.

* Current height compared to maximum height during young adulthood

§ Cumulative height loss measured during interval medical evaluation

III. PERIPHERAL BONE DENSITY MEASUREMENTS

- A. Peripheral dual energy x-ray absorptiometry (pDEXA) bone density measurement using the forearm (cortical bone), is considered **medically necessary** when either of the following criteria is met:
 1. performed for individuals (male or female) with asymptomatic primary hyperparathyroidism (PHPT) where consideration for surgery is in large part determined by bone density level; **or**
 2. when central (spine or hip) DXA measurements cannot be reliably performed and interpreted (for example: as a result of spinal instrumentation, bilateral hip replacement, or obesity).

Not Medically Necessary:

I. CENTRAL BONE DENSITY MEASUREMENTS

- A. Central bone density measurement is considered **not medically necessary** when the medically necessary criteria above is not met, including but not limited to in any of the following circumstances:
 - A.1. Routine screening for osteoporosis or osteoporosis risk for individuals who do not meet the criteria above.

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B.2. Individuals starting hormone therapy for treatment of menopausal symptoms or who are being monitored for effects of hormone therapy prescribed for menopausal symptoms and who do not meet the criteria above.

C.3. Monitoring therapy response in individuals on therapy related to osteoporosis at intervals of less than 2 years.

II. VERTEBRAL FRACTURES USING DUAL X-RAY ABSORPTIOMETRY

A. Screening for vertebral fractures using dual x-ray absorptiometry as an adjunct to bone mineral density measurement is considered **not medically necessary** in individuals not meeting the medically necessary criteria above.

III. PERIPHERAL BONE DENSITY MEASUREMENTS

A. Peripheral dual energy x-ray absorptiometry (pDEXA) bone density measurements are considered **not medically necessary** for all indications not listed above.

B. Peripheral bone density measurements using a method other than dual energy x-ray absorptiometry (pDEXA), are considered **not medically necessary** for all indications, including but not limited to, the following methods:

1. Radiographic absorptiometry of the fingers
2. Single energy X-ray absorptiometry (SEXA)
3. Single photon absorptiometry (SPA)
4. Dual X-ray and laser (DXL)
5. Ultrasound of the heel
6. Pulse-echo ultrasound of the tibia.

C. Peripheral bone density measurements are considered **not medically necessary** for asymptomatic primary hyperparathyroidism if performed on any part of the body other than the cortical bone (for example, radiographic absorptiometry of the fingers, ultrasound of the heel).

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Central Bone Mineral Density Measurement

CPT

77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)
78351	Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites [DPA]

ICD-10 Diagnosis

All diagnoses

Peripheral Bone Mineral Density Measurement

When services may be Medically Necessary when criteria are met:

CPT

77081 Dual energy x-ray absorptiometry (DXA) bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg., radius, wrist, heel)

Note: The following CPT codes for peripheral bone mineral density measurement are considered not medically necessary:

76977 Ultrasound bone density measurement and interpretation, peripheral site(s), any method

78350 Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry [SPA]

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0508T Pulse echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia [Bindex®]

HCPGs

Note: The following HCPGs code for peripheral bone mineral density measurement is considered not medically necessary:

G0130 Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)

ICD-10 Diagnosis

All diagnoses

When services are Investigational and Not Medically Necessary:

For the procedure code listed above when criteria are not met or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary

CPT

76977 Ultrasound bone density measurement and interpretation, peripheral site(s), any method

78350 Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry [SPA]

0508T Pulse echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia [Bindex®]

HCPGs

G0130 Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel).

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Osteoporosis

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Osteoporosis is characterized by slow, prolonged bone loss. The National Osteoporosis Foundation (NOF) in 2014 noted that in the United States, 9.9 million individuals are estimated to have osteoporosis. In addition, 43.1 million Americans have low bone density of the hip. Approximately one out of every two Caucasian women will experience an osteoporosis-related fracture at some point in her lifetime, as will approximately one in five men. While osteoporosis occurs less frequently in African Americans, those with osteoporosis have the same elevated fracture risk as Caucasians. The incidence of osteoporosis in the U.S. is expected to increase significantly in the future as the population ages (NOF, 2014).

The goal of osteoporosis treatment is to prevent or decrease the rate of bone loss. Such treatment may include, but is not necessarily limited to calcium and vitamin supplementations, exercise and medications such as calcitonin, parathyroid hormone, estrogens, bisphosphonates (alendronate, ibandronate and risedronate), and raloxifene. Treatment planning represents a joint decision by the individual and their treating physician following discussion of the potential risks and benefits of therapy.

Bone Densitometry/Bone Mineral Density Testing- Description of Technology

Bone densitometry/BMD tests are used to measure bone mineral content in order to predict fracture risks and the need for medical therapy. BMD can be measured at several anatomical locations. Central measurements are more commonly performed because bone loss most frequently occurs in the spine and hip regions. However, there are some conditions (such as hyperparathyroidism) in which bone loss occurs more rapidly at the peripheral sites (wrist, forearm, finger or heel) and peripheral measurements may therefore be more appropriate. Peripheral BMD are generally determined by obtaining measurements at the wrist, forearm, finger or heel, while central BMD measurements are obtained by obtaining measurements from the hip or spine. BMD is typically expressed as the T-score (for example, the number of standard deviations [SD] below the mean for non-osteopenic, healthy, young women). The World Health Organization defines osteopenia as a T-score of between -1.0 and -2.5 SD, and osteoporosis as a score of -2.5 SD or more.

Bone Densitometry- Initial and Repeat Central Bone Mineral Density Measurements

There is adequate evidence to support the use of central bone density studies to assess the risk of osteoporosis in settings where the results may influence medical therapy. Studies have demonstrated the efficacy of bone mineral studies for several populations at higher risk for this process, including postmenopausal women, especially those over the age of 65, individuals currently receiving medications for osteoporosis prophylaxis, those receiving

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glucocorticoid therapy and individuals with endocrinopathies or other conditions which predispose to osteoporosis. Examples of these include: hyperthyroidism and hypothyroidism, hyperparathyroidism, corticosteroid use, and rheumatoid arthritis. Currently both the American Association of Clinical Endocrinologists (AACE) Medical Guidelines for Clinical Practice for the Prevention and Treatment of Postmenopausal Osteoporosis (Camacho, 2016) and the U.S. Preventative Services Task Force (USPSTF) statement on Osteoporosis to Prevent Fractures: Screening (2018) recommend a screening BMD scan for all women over the age of 65 (USPSTF B recommendation). The American College of Obstetricians and Gynecologists (ACOG) recommends screening for all postmenopausal women who have sustained a fracture and for all postmenopausal women with any of a broadly defined set of risk factors (ACOG, 2012).

The timing of additional studies after the initial screening is a topic of discussion. According to ACOG, after treatment has been initiated, one DEXA scan 1 – 2 years later can be used to assess the effect of treatment. If the BMD is improved or stable (no significant change), and there are no new risk factors, the DEXA does not usually need to be repeated (ACOG, 2012). This is based upon the results of several trials that evaluated the change in BMD in individuals undergoing therapy for various conditions. These studies found that change in bone density could not be meaningfully assessed until late in the second year of therapy because some individuals actually continue to lose bone density during the first year but have subsequent significant increases during the second year of therapy. Alternatively, the AACE recommends BMD monitoring for individuals undergoing therapy for osteoporosis prevention every 1 to 2 years until bone mass is stable, then, continue with follow-up DEXA every 1 - 2 years or at a less-frequent interval, depending on clinical circumstances (Camacho, 2016).

~~Gourlay and colleagues (2012) conducted a multicenter prospective study to examine data on the optimal bone density screening interval in a large cohort of women with normal BMD or osteopenia at initial screening. The participants included 4957 women, 67 years of age or older, with normal BMD or osteopenia and with no history of hip or clinical vertebral fracture or of treatment for osteoporosis, followed prospectively for up to 15 years. The BMD testing interval was defined as the estimated time for 10% of the participants to make the transition to osteoporosis before having a hip or clinical vertebral fracture, with adjustment for clinical risk factors and estrogen use. The researchers found that it would take approximately 17 years for 10% of women with normal BMD or mild osteopenia to transition to osteoporosis before having a hip or vertebral fracture, approximately 5 years for those with moderate osteopenia to transition to osteoporosis, and 1 year for those with advanced osteopenia. At the time~~

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~~of this review, the results of this study had not been incorporated into national osteoporosis screening recommendations.~~

Vertebral Fractures

Vertebral fractures (VFs) are a strong indicator of future fractures of all types (Klotzbuecher, 2000). The presence of a vertebral fracture is associated with a 2-3 fold increase in the risk of other fractures, regardless of bone mineral density status. Although elderly individuals frequently experience a vertebral fracture, many of these individuals are initially asymptomatic and clinically unrecognized. Although most of vertebral fractures are initially clinically silent, these fractures are often associated with symptoms of pain, deformity, disability, and mortality. Repeated or multiple thoracic fractures may result in restrictive lung disease, and lumbar fractures may alter abdominal anatomy, resulting in constipation, abdominal pain, distention, reduced appetite, and premature satiety (Cosman 2014). It has been estimated that approximately two-thirds of VFs are not clinically detected and one-third are discovered incidentally on lateral spine radiographs. However, lateral spine radiographs are not routinely conducted on elderly individuals due to several factors including but not limited to inconvenience and the associated radiation exposure.

Even in the absence of a bone density diagnosis, a vertebral fracture is consistent with a diagnosis of osteoporosis, and is an indication for pharmacologic therapy to reduce subsequent fracture risk. VFA has been explored as an imaging tool to proactively identify vertebral fractures. The detection of fractures in some individuals with low bone mineralization is a predictor of future fractures and allows for their risk reclassification and the potential initiation of pharmacotherapy.

Vertebral Fracture Assessment - Description of Technology

~~VFA (formerly referred to as vertebral morphometry, instant vertebral assessment and vertebral absorptiometry) uses central DEXA to obtain images of the thoracic and lumbar spine to identify vertebral fractures.~~ Image quality of VFA now approaches that of a standard radiograph. Its radiation dose is less than 1% of a comparable radiograph, and is considered quite low at (30-50 uSv). VFA can be performed using most modern DEXA machines and may be performed at the time of BMD assessment (Cosman, 2014).

Vertebral Fracture Assessment - Initial and Repeat Measurements

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Studies have investigated the use of DEXA as a screening tool for vertebral fractures as an adjunct to BMD measurements in asymptomatic individuals. These studies have reported that asymptomatic vertebral fractures may be present in up to 20% of postmenopausal women who have normal BMD measurements. Studies comparing DEXA vertebral fracture assessment to lateral spine X-rays (considered the “gold standard” for diagnosis of vertebral fractures) have shown high levels of agreement between the two techniques.

The utility of VFA is in the identification of individuals who would otherwise not qualify for treatment under the guidelines based solely on BMD measurements (Expert Panel on Musculoskeletal Imaging, 2017). Several studies have demonstrated VFA resulted in the identification of unknown vertebral fractures and led to individuals being reclassified due to the identification of a vertebral fracture. Jager and colleagues (2011) conducted a prospective diagnostic evaluation study which involved a total of 2,500 consecutive subjects referred for BMD. Study participants underwent VFA after BMD testing. Questionnaires were used to evaluate the clinician’s perceived added value of VFA. Results were evaluable for 2,424 participants (1,573 women) and were considered unreliable in 76 (3%) of the subjects. The researchers found that VFA detected an unknown vertebral fracture in 69% of the participants. Amongst the female subjects, the prevalence was 20% versus 27% found in men ($p<0.0001$). The prevalence of vertebral fractures in subjects with normal BMD was 14% (97/678), increased to 21% (229/1,100) in individuals with osteopenia and to 26% in those with osteoporosis (215/646) by WHO criteria. In 468 of 942 questionnaires (50% response rate), 27% of the referring physicians reported the results of VFA to impact patient management.

~~Kanterewicz and colleagues (2014) assessed the prevalence of vertebral fractures and minor deformities in 2,968 postmenopausal females between 59-70 years of age. Both VFA and BMD measurements were performed, and McCloskey criteria (vertebral heights below 3 SD from reference values) confirmed with the Genant method were used to define vertebral fracture. Additionally, minor vertebral deformities (vertebral heights between -2 and -2.99 SD) were assessed. The prevalence of vertebral fractures was 4.3% and 17% of the participants had minor vertebral deformities. Low BMD was frequently observed in women with vertebral fractures, with 4%, and 42% of participants demonstrating osteoporosis and osteopenia. Minor vertebral deformities were observed in nearly 40% of the subjects with vertebral fractures. Multivariate logistic regression analysis revealed that age, history of previous fracture, osteoporotic BMD, receiving anti-osteoporotic treatment, and current use of glucocorticoids were significantly associated with vertebral fracture.~~

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According to the American College of Radiology (ACR, 2017), studies have confirmed that 10%–17% of individuals with osteopenia as measured by DEXA had grade 2 or 3 vertebral fractures detected by VFA. Because as much as 50% of fragility fractures appear in postmenopausal women with T-scores greater than -2.5 , “identification of this population’s increased risk is essential for potential medical treatment that has been shown to be beneficial in multiple studies”. According to the ACR, VFA is appropriate in individuals with T-scores less than -1.0 and any one of the following:

- Women age ≥ 70 years or men age ≥ 80 years;
- Historical height loss >4 cm (>1.5 inches);
- Self-reported but undocumented prior vertebral fracture;
- Glucocorticoid therapy equivalent to ≥ 5 mg of prednisone or equivalent per day for ≥ 3 months (Expert Panel on Musculoskeletal Imaging, 2017).

Because vertebral fractures occur so frequently in older individuals and often produce no acute symptoms, the NOF (Cosman, 2014) recommends that vertebral imaging be considered for the following individuals:

- In all women age 70 and older and all men age 80 and older if BMD T-score is ≤ -1.0 at the spine, total hip, or femoral neck
- In women age 65 to 69 and men age 70 to 79 if BMD T-score is ≤ -1.5 at the spine, total hip, or femoral neck
- In postmenopausal women and men age 50 and older with specific risk factors:
 - Low-trauma fracture during adulthood (age 50 and older)
 - Historical height loss (difference between the current height and peak height at age 20) of 1.5 in. or more (4 cm)
 - Prospective height loss (difference between the current height and a previously documented height measurement) of 0.8 in. or more (2 cm)
 - Recent or ongoing long-term glucocorticoid treatment
- If bone density testing is not available, vertebral imaging may be considered based on age alone.

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The NOF also stipulates that vertebral imaging should be repeated if there is documentation of prospective height loss, new back pain or postural changes. A follow-up vertebral imaging test is also recommended in individuals who are being considered for a medication holiday, since the cessation of medication would not be recommended in individuals who have experienced recent vertebral fractures (Cosman, 2014).

The Endocrine Society guidelines on Osteoporosis in Men recommend VFA using DEXA equipment for men with osteopenia or osteoporosis who might have previously undiagnosed vertebral fractures. If VFA is technically limited or not available, lateral spine radiographs should be considered (Watts, 2012).

Peripheral Bone Mineral Density Measurements of the Cortical Bone (Forearm)

The American Association of Clinical Endocrinologists (AACE) and the American Association of Endocrine Surgeons' (AAES) position statement on the diagnosis and management of primary hyperparathyroidism indicates that losses of bone mineral density (BMD) from primary hyperparathyroidism (PHPT) are more pronounced in the forearm (cortical bone) than in the spine (trabecular bone) and hip (mixed cortical and trabecular bone) but may occur at all skeletal sites. Although forearm losses of BMD may be more commonly associated with PHPT, the benefit from surgical treatment is more notable for the hip and spine because of the morbidity and mortality associated with fracture. The position statement asserts that individuals with PHPT should undergo DXA scanning of these three sites for reliable documentation of their BMD status as a criterion for recommending parathyroidectomy.

Chappard and colleagues (2006) studied females with primary hyperparathyroidism and healthy women to assess the bone mineral density (BMD) status in primary hyperparathyroidism (PHPT). Their results suggested that low BMD at lumbar spine and femur is encountered preferentially in premenopausal women. The BMD decrease predominates at limbs in PHPT with presumably a gradient from proximal to distal part of the limbs. Indeed, the distal part of the limbs are the most affected areas in PHPT whatever the amount of cortical or trabecular bone.

The American College of Radiology and Society of Skeletal Radiology practice guideline for the performance of dual-energy x-ray (DXA) recognizes that there may be instances (extensive abdominal aortic calcification, degenerative disease of the lumbar spine or hip, scoliosis, fractures, orthopedic implants), where central DXA measurements are not feasible and alternate sites (the opposite hip, nondominant forearm, or whole body) can be used for evaluating the individual. The guideline also states that "DXA of the nondominant forearm may be useful

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in individuals who exceed the weight limit of the DXA table and in individuals with hyperparathyroidism" (ACR-SSR, 2013).

Other Peripheral Bone Mineral Density Measurements (Exclusion of Cortical Bone)

Other methods used to evaluate peripheral bone density are not in accordance with generally accepted standards of medical practice, including radiographic absorptiometry of the fingers, single energy X-ray absorptiometry (SEXA), single photon absorptiometry (SPA), dual X-ray and laser (DXL), ultrasound of the heel, pulse-echo ultrasound of the tibia.

Ultrasound Heel Densitometry versus DXA

Because of the slow changes in bone mineral density and the precision of measuring technologies, specifically DXA, monitoring response to therapy prior to 2 years is unlikely to detect changes. In addition, changes in bone mineral density at central sites (for example, hip and spine) are often not reflected by changes in bone mineral density at peripheral sites.

Nayak and colleagues (2006) conducted a meta-analysis to determine the sensitivity and specificity of calcaneal quantitative ultrasound for identifying individuals who meet the World Health Organization's diagnostic criteria for osteoporosis. DXA was used as the reference standard. Of the 1908 articles identified, 25 met the inclusion criteria and calculated the sensitivity and specificity of quantitative ultrasound over a range of thresholds. The authors found that the results of calcaneal quantitative ultrasound at commonly used cutoff thresholds do not definitively exclude or confirm DXA-determined osteoporosis and that additional research is needed before use of this test can be recommended in evidence-based screening programs for osteoporosis.

The 2011 U.S. Preventive Services Task Force (USPSTF) recommendations on screening for osteoporosis state that quantitative ultrasonography seems to be equivalent to DXA for predicting fractures. However, the current diagnostic criteria for osteoporosis utilize DXA measurements as cutoffs, and the measurements obtained from quantitative ultrasonography are not interchangeable with those obtained from DXA. The USPSTF guidelines also point out that trials evaluating drug therapies for osteoporosis use DXA measurements as inclusion criteria. Therefore, in order for quantitative ultrasonography to be relevant and clinically useful, a method for converting or adapting the results of quantitative ultrasonography to the DXA scale needs to be developed.

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Ultrasound heel densitometry may be shown to have clinical potential as a screening tool for osteoporosis, however, at the present time, data are mixed and do not indicate strong and consistent support for the routine use of ultrasound densitometry as a screening or diagnostic tool or as a means to monitor response to therapy. The full potential of this technology cannot be realized without additional studies on the precision, accuracy, reproducibility, and validity of ultrasound densitometry in the clinical setting.

Pulse-echo Ultrasound of the Tibia

Pulse-echo ultrasound of the tibia is being evaluated as a tool to assist with the identification and diagnosis of individuals considered to be at increased risk for osteoporosis and for the determination of fracture risk. At least one such device has been granted FDA premarket approval. In January 2017, the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) granted pre-market approval (K161971) for marketing Bindex® BI-2 pulse-echo ultrasound device (Bone Index, Kuopio, Finland). According to the FDA approval letter:

Bindex measures apparent cortical bone thickness at the proximal tibia and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.

The Bindex BI-2 device: is comprised of a handheld ultrasound transducer and software. Bindex BI-2 is connected to the USB port of a computer and operated with computer software. Bindex BI-2 measures the thickness of the cortical bone and calculates the Density Index (DI), a parameter which estimates bone mineral density at the hip as measured with DXA. To obtain tibial measurements, gel is applied to the skin and the ultrasound transducer is manually placed on the measurement location. The standardized measurement location is at the proximal tibia (1/3 length of tibia). The operator then manually orients the transducer perpendicularly to the surface of the cortical bone to obtain the measurement. This process is repeated five times at each measurement location. The transducer is then disinfected by removing the gel with an isopropyl alcohol moistened cloth.

The intended place in therapy for this device would be to utilize it in addition to current algorithmic fracture risk assessment tools (for example, FRAX). When the algorithmic fracture risk assessment tool suggests an intermediate

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or high risk of osteoporotic fracture, the pulse-echo device could be employed to determine whether referral for DXA scan is appropriate (in the case of confirmed intermediate risk) or not (if low risk).

Several articles have been published which explore the use of the pulse-echo ultrasound device as a tool to screen for osteoporosis (Karjalainen, 2016; Karjalainen, 2018; Schousboe, 2017). While there are no safety concerns regarding the use of pulse-echo ultrasound of the tibia, the peer-reviewed evidence exploring this technology is limited to uncontrolled, non-randomized trials evaluating Caucasian females. It has not yet been determined if the results demonstrated in the studies referenced above will be replicated in other ethnic groups. There is currently no prospective evidence showing the Bindex pulse-echo ultrasound can predict fracture risk; this evidence is essential for an osteoporosis assessment tool given that treatments are aimed at reducing fracture risk. No prospective studies demonstrating the effect of pulse-echo ultrasound of the tibia on the need for DXA scans were identified at the time of this review. Additionally, there are limited data on the correlation between tibial bone thickness and femoral bone mineral density. Also no professional medical society guidelines which recommended or supported the use of pulse-echo ultrasound of the tibia as a means to screen for or diagnose osteoporosis were identified.

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Central (Hip or Spine) Bone Mineral Density Measurement Testing and Screening for Vertebral Fractures Using Dual Energy X-Ray Absorptiometry Measurement

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Vertebral Fractures, Screening for Using Dual X-Ray Absorptiometry

History

Status	Date	Action
Revised	08/22/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. Document expanded to address central and peripheral BMD testing as well as screening for vertebral fractures using DEXA. Content of RAD.00004 Peripheral Bone Mineral Density Measurement moved to this document. Title

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Reviewed 01/24/2019

changed to “Bone Mineral Density Testing Measurement”. Updated Description, Clinical Indications, Discussion/General Information, References, Index and History sections. Updated Coding section; added CPT codes 76977, 77081, 78350, 0508T and HCPCS code G0130.

Revised 01/25/2018

Medical Policy & Technology Assessment Committee (MPTAC) review.

Updated Rationale, References and History sections of the document.

MPTAC review. Revised Clinical Indications section to indicate (1) An initial BMD screening is considered medically necessary in men greater than 70 years of age (2) Vertebral fracture assessment (VFA) is considered medically necessary when criteria are met; (3) Removed calcitonin from the list of conditions that may underlie osteoporosis; (4) Revised the not medically necessary statement for VFA to indicate that VFA is considered not medically necessary when the individual does not meet the medically necessary criteria.

Updated the Discussion/General Information, References and History sections.

Revised 11/02/2017

MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Medically Necessary Clinical

Indications section by changing bullet A from “An initial examination in menopausal or post-menopausal individuals to screen for osteoporosis. No additional criteria are required” to “Screening for osteoporosis in postmenopausal individuals 65 years of age or older”. Minor format change in the Repeat Central Bone Mineral Density Measurements section of the Clinical Indications. Updated Description/General Information, References and History sections.

Revised 11/03/2016

MPTAC review. In the Initial Central Bone Mineral Density Measurements section, revised bullet A by replacing the word “women” with the word “individuals”. Updated the References and History sections and formatting in the “Clinical Indications” section.

Revised 11/05/2015

MPTAC review. Updated review date, Description and Discussion/General Information, References and History sections of document. Removed ICD-9 codes from Coding section.

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Reviewed	11/13/2014	MPTAC review. Updated review date, Description/General Information, References and History sections of document. Updated Coding section with 01/01/2015 CPT changes; removed 77082 deleted 12/31/2014.
Reviewed	11/14/2013	MPTAC review. Updated review date, Rationale, References and History sections of document.
Reviewed	11/08/2012	MPTAC review. Updated review date, Rationale, Discussion/General Information and History sections of document.
Reviewed	11/17/2011	MPTAC review. Updated review date, References and History sections of document.
Reviewed	11/18/2010	MPTAC review. Updated review date, References and History sections of document.
	10/14/2010	Category number changed from CG-RAD-18 to CG-MED-39. Removed CPT code 77078 from the Coding section of document. Updated Website information.
Reviewed	11/19/2009	MPTAC review. Removed "Place of Service/Duration" section. Updated the review date, Discussion/ General Information, references and history sections.
	06/04/2009	Removed the passage addressing the "Interventional Society of Clinical Densitometry" from the discussion/general information section of the document.
Revised	11/20/2008	MPTAC review. Document revised to address screening of vertebral fractures using DEXA which is considered not medically necessary. Osteogenesis imperfecta and inflammatory bowel disease added to conditions which may contribute to the development of osteoporosis. Title changed to Central (Hip or Spine) Bone Density Measurement and Screening for Vertebral Fractures Using Dual Energy X-Ray Absorptiometry. Updated Discussion/General Information, References, Coding and History sections.
Reviewed	11/29/2007	MPTAC review. Updated review date, discussion/general information, references and history sections. No change in patient selection criteria.
Revised	08/23/2007	MPTAC review. Modified language in the "Repeat BMD Measurements" section to clarify that all individuals listed in bullet #3 are considered at high risk for osteoporosis. Under the NMN section, deleted the words "or cardiac

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Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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Central (Hip or Spine) Bone Mineral Density Measurement Testing and Screening for Vertebral Fractures Using Dual Energy X-Ray Absorptiometry Measurement

New

12/07/2006

prophylaxis from bullet #2. Updated the discussion/general information, place of service, references and history sections.

MPTAC initial guideline development. Guideline addresses central bone density measurements. Peripheral bone density measurement and screening of vertebral fractures using DEXA are now addressed in RAD.00004 – Peripheral Bone Mineral Density Measurement and Screening for Vertebral Fractures Using DEXA.

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